

REMARKS

This Response is submitted in reply to the non-final Office Action mailed on July 24, 2008. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-434 on the account statement.

Claims 1-30 are pending in the application. Claims 11-24 were previously withdrawn. In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. § 103(a). Applicants respectfully submit that for at least the reasons provided below, the obviousness rejection should be withdrawn.

In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP Patent No. 1020123 to Cavaliere Vesely, et al. ("*Vesely*") taken with U.S. Patent No. 6,156,355 to Shields, Jr., et al. ("*Shields*"), U.S. Patent No. 7,037,708 to Runge, et al. ("*Runge*"), WO 00/79072 to Berggren, et al. ("*Berggren*") and U.S. Patent No. 5,603,930 to Brassart, et al. ("*Brassart*") and further taken with U.S. Patent No. 4,806,368 to Reddy ("*Reddy*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claim 1 recites an orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid or derivative, present in the composition in an amount from 10⁻¹²% to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract. The presently claimed oral composition includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced effect or response with respect of the photoprotection of the skin. See, specification, page 14, lines 6-11. Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Applicants submit that the cited references, as demonstrated by the *Affidavit* submitted previously, fail to recognize the surprising and unexpected effect that the specific composition has on the photoprotection of the skin. Specifically, the *Affidavit* summarizes a controlled study performed by Applicants that demonstrates the surprising and unexpected synergistic photoprotective effects resulting from ingestion of the presently claimed composition comprising

an admixture of a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract. As is demonstrated by the study discussed in the *Affidavit*, the presently claimed composition has been found to be effective for not only preventing inflammation or irritation of the skin after exposure to ultraviolet radiation, but it has also been found effective in providing complete prophylactic protection against the immunosuppressive effects of ultraviolet radiation. Specifically, the composition of the present disclosure is able to block or reduce the adverse clinical, histological and immunological effects of solar radiation exposure on the skin.

As further supported by the study and summarized in the *Affidavit*, it is the specific combination of the probiotic lactic acid bacterium, the at least one carotenoid, and the yeast extract that provides the surprising and unexpected synergistic photoprotective effects on the skin. For example, Figure 2 of Exhibit B illustrates that the control test without UVR exposure (column 2) and the composition according to the present disclosure and having a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract (column 3) showed the greatest immunological response to the DNFB allergen, as demonstrated by the larger differences between the swelling of the right and left ears of the mice. The increased amount of swelling of the right ear of the mice tested with respect to columns 2 and 3 indicates that the skin reacted readily to the presence of the allergen on the right ear because the animal did not experience local immunosuppression due to exposure to UVR.

As also illustrated by Figure 2 of Exhibit B, the control test plus exposure to UVR (column 1), the "matrix" formula alone plus exposure to UVR (column 4), and the carotenoids alone plus exposure to UVR (column 5) all failed to block or reduce the clinical, histological and immunological effect of UVR exposure of the skin of the animal. These results are reflected in the decreased amount of swelling of the right ear of the animal, indicative of an animal immune system not acting efficiently due to immune system suppression by UVR exposure. In other words, the formulas corresponding to the data of columns 1 and 4-5 proved unsuccessful in preventing local immunosuppression resulting from UVR exposure.

Therefore, Applicants respectfully submit that the *Affidavit* and the study discussed therein clearly demonstrate the synergistic photoprotective effects on the skin of an animal that has ingested the presently claimed composition comprising a probiotic lactic acid bacterium, at

least one carotenoid and a yeast abstract. The effects of the presently claimed composition have, thus, been compared in the study set forth in the *Affidavit* to compositions having i) only carotenoids and yeast, and ii) carotenoids alone. As such, the study and *Affidavit* clearly demonstrates the efficacy of the presently claimed composition and the importance of the combination of all three components including the probiotic lactic acid bacterium, at least one carotenoid and a yeast abstract.

As further supported by the *Affidavit*, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to obtain the present claims because the cited references are directed to unrelated products that have completely different objectives.

For example, *Vesely* is directed to a beverage containing live bacteria used to increase, balance and supplement intestinal flora. See, *Vesely*, col. 3, [0016]. *Shields* is entirely directed to canine food formulations that optimize digestibility of nutrients in specific canine breeds. See, *Shields*, column 3, lines 30-36. *Runge* is entirely directed toward dry microorganism cultures and the processes for producing same. See, *Runge*, Abstract. *Berggren* is related to a sports drink that is designed to increase the energy and fluid levels in an individual, as well as reduce stress. See, *Berggren*, page 2, line 39-page 3, line 4. *Brassart* is entirely related to a biologically pure culture of a lactic acid bacterium strain. See, *Brassart*, Summary of the Invention. *Reddy* is entirely directed toward a supplement that permits the longevity of certain health promoting bacteria in tablets. See, *Reddy*, column 1, lines 10-20. As such, Applicants respectfully submit that there is absolutely no guidance in the cited references for one of skill in the art to choose the active agents and amount of agents present in the instant claims to achieve the unexpectedly improved photoprotective effect on the skin as Applicants have done.

Moreover, in contrast to the presently claimed subject matter, and as supported in the *Affidavit*, the cited references are completely unconcerned with blocking or reducing the adverse clinical, histological and immunological effects of solar radiation exposure on the skin, as demonstrated above. Consequently, the skilled artisan would have no reason to combine the cited references to arrive at a photoprotecting composition in accordance with the present claims, nor would the skilled artisan have any reasonable expectation of success in combining the cited references. Moreover, the large number of references (6) that are cited by the Patent Office to

support the present rejection itself provides evidence that the present claims are not obvious. For at least the reasons discussed above, Applicants respectfully submit that Claims 1-10 and 25-30 are novel, nonobvious and distinguishable from the cited references.

The Office Action states, in response, that there is no nexus or correlation between the invention as claimed and the results provided. Specifically, the Office Action asserts that there is no nexus or correlation between the live La1 of the *Affidavit* and the invention as claimed directed to any probiotic acid bacterium and the various species and strains of Claims 3 and 4, which do not appear to include an amount of live La1. Applicants respectfully disagree. As known by persons skilled in the art, "La1" is an abbreviation of *Lactobacillus johnsonii*. See, http://www.research.nestle.com/innovations_publications/key_innovations/La1_Sequencing.htm. *Lactobacillus johnsonii* is clearly recited in Claim 3 as an example of the probiotic lactic acid bacterium generally recited in independent Claim 1.


The Office Action also asserts that the *Affidavit* does not clearly distinguish over the art and is not probative of unexpected results since it is not commensurate in scope with the claims. Applicants respectfully disagree with this assertion and submit that the showing of the *Affidavit* is commensurate with the scope of the claims by establishing, as stated above, that the control test without UVR exposure (column 2) and the composition according to the present disclosure and having a photoprotecting effective amount of at least one probiotic lactic acid bacterium (e.g., La1 – *Lactobacillus johnsonii*), at least one carotenoid, and a yeast extract (column 3) showed the greatest immunological response to the DNFB allergen, as is demonstrated by the larger differences between the swelling of the right and left ears of the mice. See, *Affidavit*, #11. Therefore, the *Affidavit* demonstrates the photoprotective qualities of the composition recited in the claims.

Accordingly, Applicants respectfully request that the rejections of Claims 1-10 and 25-30 under 35 U.S.C. §103 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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